

*Application No.: 09/737118*  
*Page 5*

*Amendment*  
*Attorney Docket No.: S63.2-6748-US03*

**Amendments To The Drawings:**

None.

**Application No.: 09/737118**  
**Page 6**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

**Remarks**

This Amendment is in response to the Office Action dated **October 19, 2005**. This application was filed on December 14, 2000 to provoke an interference and claims 85-89 were copied from US patent 6,110,146. A Preliminary Amendment was submitted that day including the needed requirements to provoke an interference.

All claims were deemed allowable in an Office Action mailed January 18, 2005. It was noted that due to a potential interference that ex parte prosecution would be suspended for a period of 6 months. Applicant submitted Status Requests on June 23, 2005 and October 5, 2005. This Office Action has now followed.

**Supplement to Request for Interference filed December 14, 2000**

Claims 85-89 are now objected for failing to comply with a new rule effective September 13, 2004 (Rule 41.202) even though Applicant fully complied with the rules for provoking an interference in existence on the filing date of December 14, 2000. Although it is not believed that Applicant should be required to in effect refile according to a rule effective almost four years after the filing, a response is included herein.

By this letter, Applicants supplement and amend the previous letter thereby requesting additional claims be designated as corresponding to the Count. A formal request to be accorded benefit of the priority filing dates of applications claimed in this application is also being made herein. Information submitted pursuant to the requirements of 37 C.F.R. § 41.202(a) is also specifically identified herein.

**I. Request to be Accorded Benefit of Prior Applications**

Applicants hereby formally request that in the declaration of the interference they be accorded benefit of the filing date of parent U.S. Application No. 09/528,613 filed March 20, 2000 to Holman et al. (the "Holman '613 application"), now US Patent 6,416,529. That application was a division from U.S. Application No. 09/034,434 filed March 4, 1998 by Holman

**Application No.: 09/737118**  
**Page 7**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

et al (the "Holman '434 application"), now US patent 6,152,944. That application was a CIP of U.S. Patent Application No. 08/812,351 filed March 5, 1997 by Holman et al. (the "Holman '351 application"), now U.S. patent 5,893,868.

Applicants are entitled to the March 20, 2000 filing date of the Holman '613 application and to the March 4, 1998 filing date of Holman '434 application based on copendency and the assertion of priority right under 35 U.S.C. § 120. The disclosure of the present application and the parent Holman '613 and Holman '434 applications are identical. Therefore, Applicants can establish a constructive reduction to practice of the claimed invention at least as early as March 4, 1998. The disclosure of the ultimate parent Holman '351 differs from the present application in that Figures 46-55 and the discussion of those figures was added in the Holman '434 application. To the extent that the count is based on the disclosure of Holman '351, this application may claim the Holman '351 application's filing date of March 5, 1997. Applicants also formally claim the benefit of the filing date of PCF application published as WO98/39056 on September 11, 1998, based on an application date of March 5, 1998, itself claiming priority to the Holman '351 application.

## **II. Patents and Applications with which Applicants seek an Interference (37 C.F.R. § 41.202(a)(1))**

*For Holman et al.:*

09/737,118, filed December 14, 2000, pending "the present application" or "the Holman '118 application."

*For Berthiaume et al.:*

09/164,166, filed September 30, 1998, patented U.S. 6,110,146 (the "Berthiaume '146 patent").

## **III. Identification of Other Related Applications**

*For Applicants:*

08/812,351, filed March 5, 1997 (Hanson '351 application), patented as U.S. Patent 5,893,868.

09/211,376 filed December 14, 1998, (Hanson '376), a division of Hanson '351, patented

**Application No.: 09/737118**  
**Page 8**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

as U.S. Patent 6,132,450.  
09/034,434 filed March 4, 1998, (Holman '944), CIP of Hanson '351, patented as U.S. Patent 6,152,944.  
09/528,613 filed March 20, 2000, (Holman '613), a division of Holman '944, patented as U.S. Patent 6,416,529.  
10/029,354 filed October 26, 2001, (Holman '354), Continuation of Holman '613, issue fee paid.

*For Berthiaume et al.:*

None.

**IV. Proposed Count (37 C.F.R. § 41.202(a)(2))**

One Count is proposed:

1. A protective sleeve for a balloon dilatation catheter comprising:  
an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.

**V. Amended Designation of Claims (37 C.F.R. § 41.202(a)(2))**

Applicants request that the interference be declared with the following designation of claims corresponding to the Count.

*Holman et al.:* U.S. Application No. 09/737,118, claims 85-89;

*Berthiaume et al.:* U.S. Patent 6,110,146, claims 1-5.

**VI. Detailed Basis for Designation of Claims (37 C.F.R. § 41.202(a)(2))**

In the following analysis, each claim is analyzed from the perspective of the Count being taken as prior art to the claim.

**Application No.: 09/737118**  
**Page 9**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

**Berthiaume et al, US 6,110,146**

**Claim 1:** A protective sleeve for a balloon dilatation catheter comprising:  
an elongate tubular member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.

Claim 1 is identical to the Count so it is properly designated as corresponding to the Count.

**Claims 2-5:**

2. A protective sleeve as defined in claim 1, wherein the slit extends along a plane that includes a longitudinal axis of the tubular member.
3. A protective sleeve as defined in claim 1 wherein the slit is helical.
4. A protective sleeve as defined in claim 1 further comprising:  
an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.
5. A protective sleeve as defined in claim 4 wherein the outer sleeve is elastomeric.

Claims 2-5 are the additional claims of the Berthiaume '146 patent which Applicants have copied as application claims 86-89. The Berthiaume '146 patent claims and Applicants' corresponding claims 86-89 correspond to the Count and depend from a claim corresponding to

**Application No.: 09/737118**  
**Page 10**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

the Count. Applicants, as senior party, are *prima facie* entitled to the subject matter of these claims. Claims 86-89 correspond to the count because they are anticipated or obvious variants of the subject matter of the count under 36 CFR 412.07b.

**VII. Claim Chart showing interfering subject matter 37 C.F.R. § 41.202(a)(3)**

Berthiaume U.S. 6,110,146	Holman U.S. Application 09/737,118	Interfering Subject Matter
1. A protective sleeve for a balloon dilatation catheter comprising: an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	85. A protective sleeve for a balloon dilatation catheter comprising: an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.	The claims are identical to each other and to the Count. The two-way unpatentability test under 37 C.F.R. § 41.203(a) is satisfied on the basis that both the Berthiaume '146 patent and the Holman '118 application have a claim identical to the proposed count.

Although 37 C.F.R. § 41.203 is understood to only require a showing of two-way unpatentability between one claim of each party for each count, it bears repeating that Berthiaume '146 claims 1-5 and Applicants' claims 85-89 are identical. Therefore, each matching pair of dependent claims also meets the two-way unpatentability test of § 41.203(a).

**Application No.: 09/737118**  
**Page 11**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

**VIII. Detailed Explanation Why Applicants Will Prevail On Priority (37 C.F.R. § 41.202(a)(4))**

Applicants are entitled to a constructive reduction to practice at least of as early as March 4, 1998. The instant application is a continuation of US Application 09/528,613 filed March 20, 2000 which was a divisional Application of 09/034,434 filed March 4, 1998 which was a Continuation-In-Part application from 08/812,351 filed March 5, 1997, now U.S. Patent 5,893,868. U.S. 6,110,146 to Berthiaume was filed September 30, 1998. The instant application, therefore, predates Berthiaume in excess of 18 months.

Applicants are further entitled to an invention date earlier than March 4, 1998, based upon at least a conception prior to that date.

**X. Written Description Claim Chart (37 C.F.R. § 41.202(a)(5))**

Support in the application for claims 85-89, the claims copied from the Berthiaume '146 patent:

**Claims of Patent corresponding to proposed count:**

Claim 1 of Berthiaume corresponds to the proposed count verbatim. Claims 2-5 dependent thereon correspond to the proposed count. Claim 6 corresponds to the proposed count by including the protective sleeve of claim 1 and a balloon catheter.

1. A protective sleeve for a balloon dilatation catheter comprising:  
an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.

*Application No.: 09/737118*  
*Page 12*

*Amendment*  
*Attorney Docket No.: S63.2-6748-US03*

**Claims of application pending in application within one year of patent issuance:**

Claims 85-90 added above.

**Correspondence of Claim 86-89, 90 to the Count:**

Claims 86-89 are dependent claims from independent claim 85 listed above. Claim 90 refers in the protective sleeve from claim 86 and further includes a balloon catheter.

**Application of Claims 85-90 to the Specification §1.607 (a)(5) & (a)(6)**

85. A protective sleeve for a balloon dilatation catheter comprising:

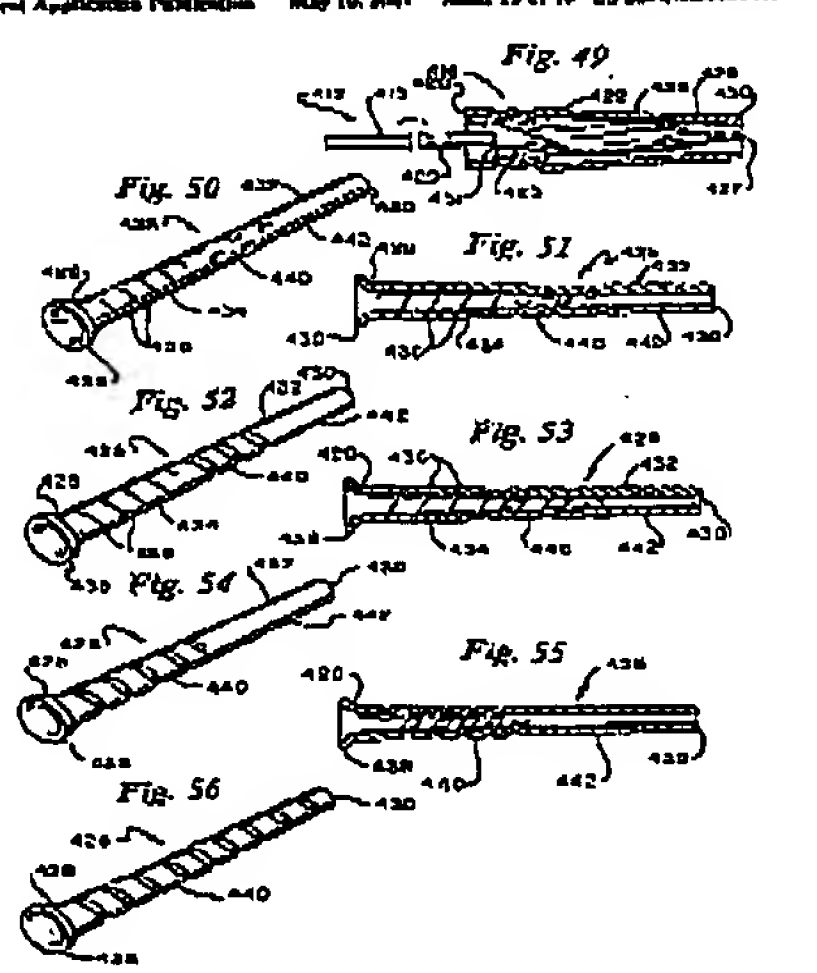
an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.

Copied Claim	09/737,118; 09/528,613; 09/034,434
<p>85. A protective sleeve for a balloon dilatation catheter comprising:</p> <p>an elongate member having a neck portion and a slit extending along the entire length of the tubular member from a proximal end to a distal end thereof, wherein a distal portion of the tubular member is flared from the neck portion to the distal end of the tubular member to define an enlarged funnel-like opening.</p>	<p>Figures 46-56 of 09/737,118; 09/528,613; 09/034,434 show the invention of the Count. The protective sleeve is element 426 of Figs. 49-56. The elongate member is tube 432 which has two ends 428 and 430 and a slit 436 extending the entire length in Fig. 56. A flare 438 creates the funnel-like opening of the Count. See Fig. 8, Page 13, lines 28 to page 14, line 4 of 09/737,118; 09/528,613; 09/034,434 and Fig. 8, Column 7, lines 40-50 of US Patent 5,893,868 which is the 08/812,351 application.</p> <p>Outer sleeve balloon protector in the form of a polymeric tube 60 with flared proximal end 62, flared distal end 64 and longitudinal slit 37</p>



Application No.: 09/737118  
Page 13

Amendment  
Attorney Docket No.: S63.2-6748-US03

	<p>Parent Application Publication May 10, 2006 Sheet 19 of 19 1/3 2006/0031128 A1</p> 
<p>87. A protective sleeve as defined in claim 85 wherein the slit is helical.</p>	<p>Figures 46-56 show the slit 436 as helical.</p> <p>See Figs. 9c,g , page 14, lines 5-8 as a spiral sleeve 66.</p>
<p>88. A protective sleeve as defined in claim 85 further comprising: an outer sleeve disposed about those portions of the tubular member proximal of the flared distal portion, the outer sleeve being configured to maintain the slit of the tubular member in a closed configuration.</p>	<p>Paragraph 76: Referring to FIG. 8, an inner sleeve, outer sleeve or singular sleeve balloon protector of the present invention may also be provided in the form of a polymeric tube 60 with flared proximal end 62, flared distal end 64 and a longitudinal slit 37.</p> <p>Paragraph 12: The second removable (outer) sleeve is positioned over the first (inner) sleeve, the outer sleeve having a constrictive relationship with the inner sleeve. The outer sleeve thereby provides an additional compressive force to reduce the profile of the constricted balloon.</p> <p>Page 14, lines 16 - 20 - may be used as an inner sleeve with any suitable outer sleeve.</p>
<p>89. A protective sleeve as defined in claim 88 wherein the outer sleeve is elastomeric.</p>	<p>Paragraph 77. A balloon protector according to the present invention may be a spiral sleeve 66 made of a polymeric material or a metal ribbon. It can also be formed by spiral cutting a tube to be the balloon protector, in a configuration as shown</p>

**Application No.: 09/737118**  
**Page 14**

**Amendment**  
**Attorney Docket No.: S63.2-6748-US03**

	<p>in FIGS. 9a-h and j and as shown at FIGS. 4a-b. This balloon protector conforms to diameter changes throughout the length of the collapsed balloon, and in a preferred embodiment has a pre-mounted inner diameter which is less than the outer diameter of the collapsed balloon to provide radial compression when applied on the balloon. The radial strength of the spiral sleeve is related to the material of which the sleeve is made, the pitch of the spiral, the wall thickness of the sleeve and the inner diameter of the sleeve. A preferred material for this balloon protector is LDPE.</p> <p>Page 15, line 5, the spiral sleeve will conform around all portions and compress them. Page 14, lines 13-14 - a preferred material for this balloon protector is LDPE.</p>
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It is noted that this application, 09/737,118 ('118) is identical to its parent, 09/528,613 ('613) filed on March 20, 2000, now U.S. Patent 6,416,529 since it was a continuation. The '118 application is also identical to 09/034,434 ('434) filed March 4, 1998, now U.S. Patent 6,152,944 since the '613 application was its division. Therefore, the claim chart provided shows a written description for each claim in the prior application under 37 CFR 41.202(a)(6) since all three applications had identical specifications.

The chart has been amended to specify the three identical applications '118, '613 and '434 all have the same support for the claims as per 37 CFR 41.202(a)(6). In addition, the chart indicates that application 08/812,351 ('351) filed March 5, 1997, now U.S. Patent 5,893,868 was the parent to the '434 application, which was a CIP in which Figures 46-55 and supporting written description was added. The claim chart indicates that the '351 application had support for claim 85 (the count) in Figure 8, Column 7, lines 40-50 as shown in the issued patent, US Patent 5,893,868. Thus, it is contended that applicant has provided the required chart showing constructive reduction to practice for each of the prior applications to be accorded benefit.

*Application No. 09/737118*  
*Page 15*

*Amendment*  
*Attorney Docket No. S63.2N-6748-US03*

**Prima Facie Showing of Entitlement to Judgment**

The instant application is a continuation application (and therefore identical to) of US Application 09/528,613 filed March 20, 2000, which was a divisional application (and therefore identical to) of 09/034,434 filed March 4, 1998, which was a Continuation-In-Part application from 08/812,351 filed March 5, 1997, now U.S. Patent 5,893,868. U.S. 6,110,146 to Berthiaume was filed September 30, 1998. The instant application, therefore, effectively predates Berthiaume in excess of 18 months. A copy of the Berthiaume patent accompanies this Preliminary Amendment. Moreover, the published PCT application WO 98/39056 on September 11, 1998 anticipates Berthiaume under 35 U.S.C. 102(b).

**Double Patenting Rejection**

Claims 85-89 were rejected under the judicially created doctrine of obviousness type double patenting over claims 1-28 of US Patent 6,416,529, over claims 1-35 of US Patent 6,152,944, over claims 1-17 of US Patent 6,132,450 and over claims 1-26 of US Patent 5,893,868. A Terminal Disclaimer is attached which overcomes the rejection.

*Application No. 09/737118*  
*Page 16*

*Amendment*  
*Attorney Docket No. S63.2N-6748-US03*

### CONCLUSION

In light of the above comments, allowance of claims 85-89 is respectfully requested. It is further requested, as to claims 85-89 that an interference be declared and that priority of invention be adjudged to the instant Applicant.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: May 4, 2006

By: \_\_\_\_\_

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Enc: Terminal Disclaimer

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